APACMed Digital Health Reimbursement Policy Forum 2024

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The second edition of the Asia Pacific Medical Technology Association's (APACMed) Digital Health Reimbursement Policy Forum was held on June 20, 2024, with participants from Singapore, Australia, Japan, South Korea, France, and the U.S. This year's forum aimed to build upon last year's discussions, with a focus on the reimbursement of AI-based platforms. The forum was hosted by APACMed in collaboration with the Medical Technology Association of Australia (MTAA), the Korea Medical Devices Industry Association (KMD and the American Medical Devices and Diagnostics Manufacturer's Association of Japan (AMDD), with EVERSANA serving as the knowledge partner.

The agenda featured insights, trends and case studies on the current applications of AI in the digital health landscape. It also covered the digital health reimbursement landscape across APAC, the U.S. and Europe, promoting peer-to-peer learning and the sharing of best practices. Additionally, the forum focused on co-creating and validating policy frameworks for broader adoption as a group exercise.

In 2023, in the inaugural edition, the forum highlighted the fragmented nature of reimbursement schemes across APAC, particularly for digital health technologies, and emphasized the need for a high-level, fit-for-purpose umbrella framework aligned with international standards to enable the reimbursement of digital health solutions in APAC. The importance of clinical evidence from randomized controlled trials (RCTs) and real-world data (RWD), the relatively muted patient voice in the reimbursement discussions, and the need for clear and transparent evidence requirements to foster optimal investment were also discussed last year.

To move the discussion forward in 2024, the Forum yet again brought together a diverse group of stakeholders, including government payers, individuals from academia, representatives from trade associations and MedTech industry experts.

The forum comprised three sessions:

Session 1: This set the stage for the day's deliberations by providing a comprehensive introduction to AI in healthcare. This session covered the basics of AI technologies, their current applications in the medical field and their potential impact on healthcare delivery. With this foundational understanding, participants were better prepared to engage in the subsequent discussions and activities throughout the day.

Session 2: This involved individual presentations on the status of digital health technology reimbursement and best practices from country representatives from Japan, Korea, Australia, Singapore, the U.S. and the EU (France). Each representative provided a detailed overview of their country's current policies, challenges and successes in the reimbursement of digital health technologies. Interactive Q&A segment and open discussions followed, allowing participants to delve deeper into specific issues, share insights and explore opportunities for cross-border collaboration and learning.

Session 3: This featured a case study discussion involving an AI-enabled diagnostic platform and a proposed reimbursement framework. This session was led and moderated by EVERSANA members at each location, ensuring expert guidance and facilitation. The discussion included an in-depth analysis of the case study, exploration of the challenges and opportunities associated with AI-enabled diagnostics, and evaluation of the proposed reimbursement framework. The insights and feedback gathered during this session contributed to the development of actionable recommendations for broader implementation. The policymakers shared the current status and upcoming priorities relative to digital health reimbursement in their jurisdictions.

Summary of Insights

Session 1: Introduction to AI in Healthcare

AI in healthcare refers to integrating artificial intelligence technologies such as machine learning and natural language processing to enhance medical processes and decision-making. AI technologies are applied in areas such as chronic care management, preventive care, triage and diagnosis, diagnostics, clinical decision support and care delivery.

For instance, AI algorithms can analyze complex medical data to assist in diagnostics, predict patient outcomes and personalize care plans. In chronic care management, AI systems can monitor patient health data continuously, identifying patterns that might indicate potential issues.

Preventive care is another area where AI can add value, using predictive analytics to identify at-risk populations and suggest preventive measures. AI-driven diagnostics can enhance the accuracy of medical imaging interpretation, reducing human error and ensuring timely and accurate diagnoses. In clinical decision support, AI tools can provide healthcare professionals with evidence-based recommendations, helping them make informed decisions quickly. AI's role in care delivery includes automating administrative tasks, freeing up healthcare providers to focus more on patient care.

Examples of AI-embedded medical devices discussed included:

- NS018_055, Insilico's lead-pipeline candidate, received the FDA's first orphan drug designation for an AI-discovered drug targeting idiopathic pulmonary fibrosis (IPF). Utilizing AI to identify a novel target and design small molecules, this drug represents a potential first-in-class treatment with broader applications in kidney and skin fibrosis. Phase II trials began in early 2024, following positive Phase I results in safety and tolerability.
- Nodoca, an AI-powered throat camera, has been approved and reimbursed as a medical device for diagnosing influenza. It analyses throat images for signs of inflammation and other indicators, enhancing diagnostic accuracy with patient data integration. Developed with over 500,000 images, Nodoca complements antigen tests and is widely used by general practitioners. The ongoing collection of images aims to improve machine learning and extend diagnostics to more diseases.

Examples of AI-embedded medical devices (1/6)

Uses of Ai in Healthcare

Patient Monitoring and Health Surveillance

Product	Description
CarePredict	An AI-embedded wearable device to monitor elderly individuals living at home. It tracks activity levels, sleep patterns, and heart rate using bio sensors.
biofourmis	This platform uses wearable biosensors and mobile apps to collect patient health data (vitals, activity, sleep). Biofourmis then leverages AI to analyze this data and identify patterns to predict potential health problems before they occur.
AiCure	A medication adherence platform that uses a smartphone camera to monitor if a patient takes their medication as prescribed. The app can remind patients to take their medication and track their progress over time.
cardiomo	Cardiomo leverages AI for analyzing ECG data. AI algorithms can identify subtle abnormalities or patterns indicative of potential heart conditions like arrhythmias or heart failure.

Presence in APAC

Examples of AI-embedded medical devices (2/6)

Uses of Ai in Healthcare

Telehealth and Remote Care

Product	Description
Medtronic	A continuous glucose monitoring (CGM) system for diabetes management. It analyzes blood sugar trends to allow proactive insulin dosing adjustments.
PHILIPS	A remote patient monitoring platform for chronic conditions. AI analyzes data from wearables to identify trends and potential health risks, allowing for early intervention.
GYANT	AI-powered healthcare chat that guides patients to the right care (self-care advice or specialist referral) and improves efficiency for both patients and providers.
EJENTA	AI-powered "intelligent agent" platforms that monitor activity, analyze data, and provide personalized support. Can be used to remotely track patients with chronic conditions and offer personalized guidance.

Presence in APAC

Examples of AI-embedded medical devices (3/6)

Uses of Ai in Healthcare

Patient Diagnosis and Early Detection

Platform	Description
twill	Twill's platform utilizes AI/ML and natural language processing to analyze mental health conversations to identify patterns and improve treatment plans.
merative	A cloud-based platform leveraging AI to streamline data management and analysis, allowing more accurate diagnosis and reducing administrative burdens.
iz.ai	AI-powered platform that streamlines patient record management and accelerates decision-making through real-time analytics. Enhances communication, improves treatment outcomes, and reduces recovery times.
ENLITIC	AI platform that enhances health data analysis for precise diagnosis and clinical decision support. Identifies early health signs and gives accurate health overviews, enabling informed treatment decisions

Presence in APAC

Examples of AI-embedded medical devices (4/6)

Uses of Ai in Healthcare

Drug Discovery and Development

Company	Description
eurofins	SAFIRE technology hamesses AI and proprietary Eurofins Discovery data to enhance drug discovery, offering a suite of AI models that predict ADMET outcomes quickly and accurately
AbCellera	Develops antibody therapeutics using AI. Analyzes the immune system to identify potential antibodies, leveraging its proprietary technologies e.g., single B-cell sequencing and the Celium visualization software
Benevolent AI	Specializes in AI-driven drug discovery. Benevolent Platform features tools like the Knowledge Graph and machine learning models to analyze biomedical data and literature for drug repurposing and development
bioxcel therapeutics	Focuses on drug development that utilizes artificial intelligence to identify drug candidates across neuroscience and immuno-oncology

Presence in APAC

Examples of AI-embedded medical devices (5/6)

Uses of Ai in Healthcare

Mental Health Support

Platform	Description
Meru Health	A digital mental health AI-powered app that provides individualized treatment regimens that are catered to each user's particular needs as well as online counselling and coaching.
headspace health.	A mindfulness and meditation app that employs AI algorithms to offer users customized recommendations It helps users consistently maintain their mental health objectives.
Woebot Health	AI-driven chatbot that employs cognilive-behavioral therapy methods to assist users in managing their mental health. It offers personalized discussions, daily check-ins, and mood maniloring
wysa	An Artificial chatbot that promotes mental welhess through cognitive behavioral therapy methods. features user-specific dialogues, guided meditation, and mood tracking.

Presence in APAC

Examples of AI-embedded medical devices (6/6)

Uses of Ai in Healthcare

Genomics and Precision Medicine

Company	Description
FABRIC GENOMICS	A software genomics company specializing in end-to-end analysis, interpretation, and reporting of next - generation sequencing (NGS) data. Leverages AI to identify relevant genetic variants and predict their potential impact on health.
deep genomics	Leverages AI to streamline drug development, focusing on RNA-based therapies. The AI platform efficiently processes complex RNA biology data to identify novel therapeutic targets and evaluate potential treatments.
illumina	A leader in DNA sequencing and array-based technologies. Its AI algorithm PrimateAI-3D can predict disease-causing genetic mutations in patients with unprecedented accuracy.
SOPHiA GENETICS	Uses AI to analyze genetic data for diagnosing and treating diseases like cancer and inherited disorders. Provides precise insights by interpreting complex genomic datasets, facilitating personalized medicine.

Presence in APAC

Session 2: Country Presentations Summary

SINGAPORE

- The Agency for Care Effectiveness (ACE) supports funding decisions by the Ministry of Health's Medical Technology Advisory Committee (MTAC).
- Digital health technologies (DHTs) must demonstrate clinical and economic value to be considered for reimbursement. These technologies must be registered with the Health Sciences Authority (HSA) as "software as a medical device" (SaMD).
- The reimbursement landscape includes thorough health technology assessments (HTAs) to ensure that technologies provide significant health benefits and are cost-effective.
- The ACE also focuses on driving better decision-making in healthcare by setting high standards for DHT evaluation, addressing gaps in conventional HTA methods and developing a new HTA evaluation framework specifically for DHTs.
- Additionally, ACE works on integrating AI technologies into existing healthcare frameworks, ensuring they meet safety and efficacy standards before being approved for public funding.

KOREA

- The Health Insurance Review and Assessment Service (HIRA) and the Ministry of Food and Drug Safety (MFDS) are key agencies in evaluating and approving digital health technologies.
- The Innovative Health Technology (IHT) system allows for temporary reimbursement for digital health technologies classified as medical devices. The assessment process includes criteria such as market creation potential, technological differentiation and clinical utility.
- The reimbursement mechanism involves temporary listing with a unique code for up to three years, allowing companies to select reimbursement options based on their marketing strategy and patient burden. Regular monitoring and evaluation of usage patterns, compliance and social impact are conducted to ensure the efficacy and cost-effectiveness of the listed technologies.
- Korea's approach involves collaborative efforts with international bodies to align their frameworks with global standards, facilitating smoother cross-border adoption of innovative health technologies.

AUSTRALIA

- Australia's reimbursement landscape is managed by the Medical Services Advisory Committee (MSAC), which evaluates new medical services for public funding. The Therapeutic Goods Administration (TGA) regulates medical devices, including software and AI technologies.
- Health technologies are reimbursed through federal and state governments, as well as private health insurance. The MSAC's evaluation process involves clinical trial data, real-world data and cost-effectiveness analysis to inform funding decisions.
- The Australian government is committed to transforming healthcare through digital health initiatives, focusing on improving accessibility, efficiency and patient outcomes. The Digital Health Blueprint outlined the vision for a connected and sustainable health system by 2033. Australia's strategy also includes significant investments in telehealth infrastructure and digital literacy programs for healthcare professionals to ensure effective implementation and use of new technologies.

JAPAN

- In Japan, almost all medical devices are reimbursed under the National Health Insurance (NHI) system. The evaluation process requires regulatory approval, clinical and non-clinical evaluation, and classification based on medical utility.
- Its reimbursement models are evolving to incorporate performance-based metrics and real-world effectiveness. Examples of AI technologies integrated into medical devices include diagnostic tools that improve accuracy and efficiency. The cost accounting method for software as medical devices includes detailed breakdowns of material costs, administrative selling costs, R&D expenses and distribution costs. These factors ensure that the expense is justified and limited to the necessary costs for providing the software's functions.
- Japan's approach also includes regular updates to its regulatory guidelines to keep pace with rapid technological advancements, ensuring that their healthcare system can quickly adapt and integrate new innovations.

FRANCE

- PECAN is an initiative by the French Ministry of Health and Prevention aimed at expediting patient access to innovative digital medical devices (DMDs). Launched in April 2023, PECAN offers a one-year transitional and temporary reimbursement to DMDs that demonstrate potential clinical or organizational benefits. This fast-track approach includes a parallel evaluation by the Haute Autorité de Santé (HAS) and the Agence du Numérique en Santé (ANS), resulting in a ministerial decision on reimbursement eligibility.

- PECAN involves several key steps: application submission, eligibility verification, initial assessment and a one-year reimbursement period with clear pricing rates. Successful DMDs can apply for permanent reimbursement under the common law after this period. The predefined financial compensation includes a monthly technical fee for telemonitoring activities and a fee structure for digital therapeutics (DTx) set at €435 for the first trimester and €38.3 per month thereafter.

- PECAN's implementation reflects France's broader digital health strategy, which includes various funding programs, such as the Digital Health Acceleration Strategy and the Medical Device Plan. By fostering an environment conducive to digital health innovation, PECAN aims to position France as a leader in the digital health sector. Additionally, PECAN aligns with European efforts to harmonize the evaluation and reimbursement of DMDs, thereby promoting cross-border collaboration and patient access to cutting-edge digital health solutions.

U.S

- The Centers for Medicare and Medicaid Services (CMS) oversee various reimbursement mechanisms for medical technologies, including digital health and AI devices. Medicare, a key CMS program, provides health coverage primarily for individuals age 65 and older and persons with qualifying disabilities.

- Reimbursement under Medicare involves navigating three main pathways: national coverage determinations (NCDs), local coverage determinations (LCDs) and claim-by-claim adjudications. NCDs, which are limited to three to four annually, are comprehensive reviews determining whether a medical item or service is reasonable and necessary for the Medicare population. LCDs are handled by Medicare Administrative Contractors (MACs) and are specific to regions. The majority of coverage decisions are made on a claim-by-claim basis by MACs.

- To qualify for reimbursement, manufacturers must align their products with Medicare's benefit categories and settings of use, such as hospital, physician's office or home use. For digital and AI devices, CMS emphasizes understanding the device's intended use and applicable benefit categories. CMS does not directly reimburse manufacturers but rather pays healthcare providers, such as hospitals, physician practices and durable medical equipment suppliers.

- CMS provides a detailed guide for medical technology companies, available on its website, covering coding, coverage and payment. This guide includes information on the statutory requirements and processes for obtaining Medicare reimbursement. CMS also collaborates with the Food and Drug Administration (FDA) for pre-market approvals and clinical trials, encouraging manufacturers to engage with both agencies early in the product development process.

- Moreover, CMS has pathways for covering investigational devices and routine costs in clinical trials, facilitating the integration of new technologies into the Medicare system. The agency emphasizes evidence-based care standards, requiring peer-reviewed evidence to demonstrate that new technologies improve health outcomes for the Medicare population. This comprehensive approach ensures that Medicare beneficiaries have access to innovative and effective medical technologies.

Session 3: Case Study: AI in Healthcare

Product X: AI-Powered Clinical Decision Support Solutions

Product X is a set of AI-powered image-based clinical decision support solutions designed to assist in the analysis of CT/X-ray images. The software provides annotated clinical images, quantifications, structured findings and comprehensive reports, aiming to improve diagnostic accuracy and efficiency.

Discussion Points

The discussion on Product X centred on its various evaluation parameters that were drawn from

APACMed's proposed "Digital Health Evaluation Framework," which included safety and clinical effectiveness, technical aspects, usability, interoperability, economic impact, patient and social aspects, organizational readiness and data security.

Participants evaluated the clinical success rate and impact on patient outcomes, assessed the infrastructure requirements and integration into existing systems, and considered user experience and ease of use for healthcare professionals. They also discussed the connectivity with other data sources for a seamless workflow, analyzed the cost-benefit ratio and potential savings in healthcare delivery, and evaluated the impact on patient care, interaction and empowerment. The organizational aspects considered the readiness of the healthcare system to adopt AI technologies and the training needed for staff, while data security focused on ensuring robust measures and compliance with regulations.

Participant Feedback and Framework Rating

Participants rated the framework on various parameters, discussing its strengths and areas needing improvement. The overall consensus was that while the framework was robust for assessing AI technologies, it required further refinement to address emerging challenges and ensure comprehensive evaluations.

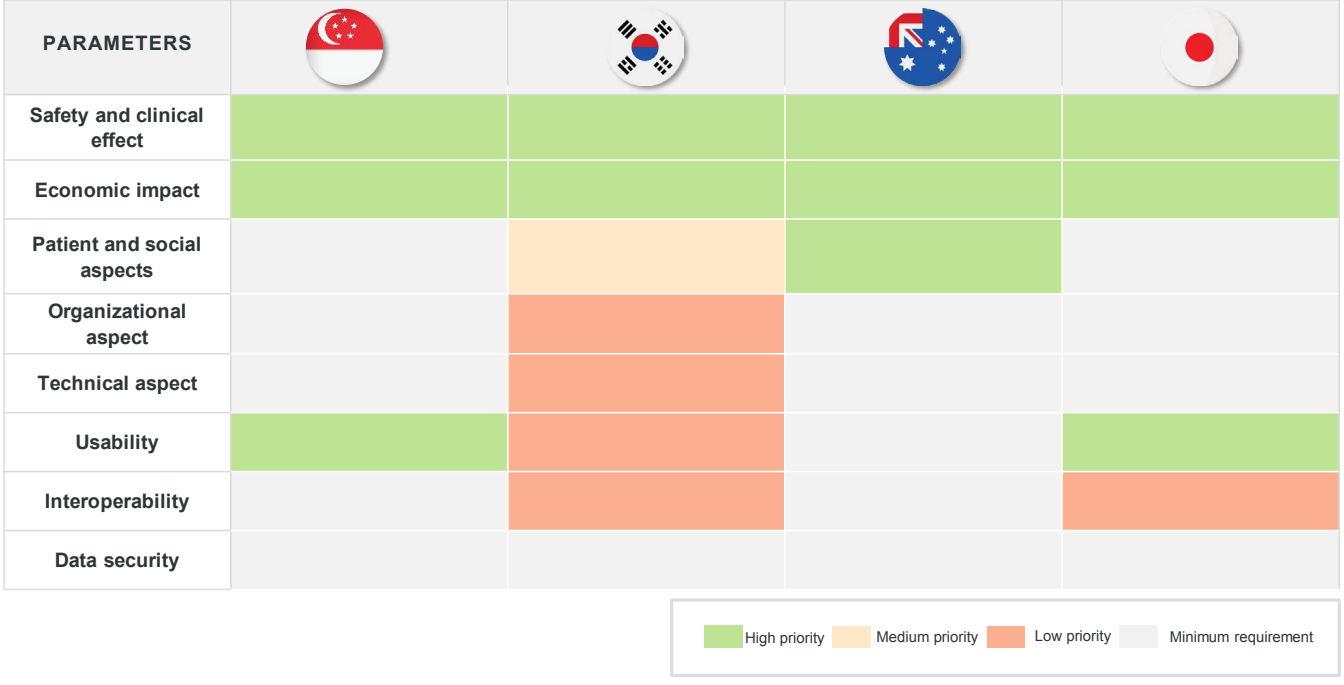
Participants reviewed the adequacy of current pathways in their countries, noting that while existing frameworks provide a solid foundation, they must be updated to keep pace with technological advances.

Singapore is currently developing HTA guidelines specific to DHTs. In **Korea**, the Innovative Health Technology (IHT) system was praised for its temporary reimbursement mechanism. However, the temporary reimbursement fee is low, and it requires more clarity in long-term assessments. ,

Australia's system was commended for its comprehensive evaluations, but it requires more streamlined processes for emerging technologies and guidelines of HTA for AI alone, as the current guidelines are only for AI associated with devices. **Japan's** move from evidence-based decisions to data-driven decisions for DHTs is effective and needs adjustments to better incorporate performance-based metrics.

Participants agreed that while the framework provides a structured approach to evaluating AI technologies, ongoing collaboration with and continuous feedback from various stakeholders are essential for its evolution and effectiveness. This feedback loop would ensure that the framework remained relevant and adaptable to the fast-paced advancements in AI and digital health technologies.

Safety and clinical effectiveness and economics impact were rated as the most important parameters for the evaluation of AI-enabled platforms.



Recommendations for Reimbursement of AI-Based Medical Devices in APAC

Based on the discussions and insights from the forum, the following next steps are recommended to advance the reimbursement of AI-based medical devices in the APAC region:

Establishing Clear Regulatory Frameworks

Governments should establish clear and transparent regulatory frameworks tailored to the unique characteristics of AI-based medical devices. This includes developing guidelines for the evaluation of clinical effectiveness, safety and economic impact.

Collaboration with international bodies, such as the International Medical Device Regulators Forum (IMDRF) and Global Harmonization Working Party (GHWP) can help harmonize standards and facilitate global market access.

Enhancing Health Technology Assessments(HTAs)

HTAs should be updated to include specific criteria for AI technologies, considering their dynamic nature and the continuous learning aspect of AI algorithms.

Governments should invest in building capacity for conducting robust HTAs, including training for evaluators and incorporating real-world evidence in the assessment process (FDA).

Promoting Cross-Border Collaboration

APAC countries should foster regional collaboration to share best practices, data and resources. This can be achieved through joint initiatives, regional workshops and collaborative research projects.

Establishing a regional task force to oversee the implementation of aligned standards and guidelines can streamline the approval and reimbursement process across countries.

Investing in Digital Infrastructure

Governments should prioritize investments in digital infrastructure to support the integration of AI technologies in healthcare. This includes enhancing data connectivity, interoperability and cybersecurity measures to protect patient data.

Engaging Stakeholders in the Development Process

Continuous engagement with stakeholders, including healthcare providers, patients, industry representatives and policymakers, is essential to ensure that the reimbursement frameworks are practical and meet the needs of all parties involved. Feedback mechanisms should be established to gather input and continuously refine the frameworks based on real-world experiences and advancements in technology (FDA).

By taking these steps, APAC countries can create an environment conducive to the adoption and reimbursement of AI-based medical devices, ultimately improving healthcare outcomes and fostering innovation in the region.

Conclusion

The second edition of the Digital Health Policy Reimbursement Forum emphasized the need for a cohesive and refined reimbursement framework for digital health technologies, particularly AI-embedded devices across APAC. Continuous dialogue and collaboration among policymakers, industry experts and stakeholders are essential to advance the adoption and integration of digital health solutions, ultimately improving healthcare delivery and patient outcomes.

The forum concluded that while existing frameworks are robust, they must be continuously updated and refined to address the rapid advances in AI and digital health technologies. International collaboration is key to harmonizing standards and facilitating the cross-border adoption of innovative health technologies. Future forums should continue to build on these discussions, aiming to create a more integrated and supportive environment for digital health innovation in the APAC region.

Contacts:

Anirudh Sen

Director & Head, Market Access & IVD
APACMed
anirudh_sen@apacmed.org

Amardeep Udeshi

Senior Vice President
EVERSANA
amardeep.udeshi@eversana.com

Annex: Digital Health Reimbursement Policy Forum 2024 Participants

Singapore

Dr. Soon Swee Sung	Senior Lead Specialist, Health Technology Assessment	Agency for Care Effectiveness
Ankit Kulshreshta	Senior Principal	EVERSANA
Arif Fahim	Regional Director, Global Health Economics & Reimbursement	Abbott
Dr. Julian Sham	APAC Clinical Digital Transition Lead	Roche Diagnostics
David Vu	Chief Operating Officer	Diagnostics Development Hub, Agency for Science, Technology and Research
Chan Beng Seng	Deputy Chief Executive	ALPS Healthcare
She Hui Tan	Principal Analyst	Agency for Care Effectiveness
Josephine Hong	Head of Marketing, APAC	Philips
Akie Seno	Director, Market Access Asia Cluster	Smith + Nephew
Dr. Wang Yi	Assistant Professor	Saw Swee Hock School of Public Health, National University of Singapore
Dr. Chen Wenjia	Assistant Professor	Saw Swee Hock School of Public Health, National University of Singapore
Joelynn Tay	HE&R Manager, APAC	Abbott
Shaillender M.	Engagement Manager	EVERSANA
Haelim Choi	Analyst	EVERSANA
Binderiya Makhbal	Assistant Manager, Market Access	APACMed
Kamalesh Logarajan	Finance and Administrative Associate	APACMed

EVERSANA Team Members

Nishit Patadia	Engagement Manager	EVERSANA
Indraneel Chatterjee	Senior Consultant	EVERSANA
Rishabh Raj	Associate Consultant	EVERSANA
Li Huey Low	Associate Consultant	EVERSANA

South Korea

Ms. Young Ae Jeong	Director General, Department of Benefits Listing	Health Insurance Review & Assessment Service (HIRA), South Korea
Dr. Jae-Yong Shin	Assistant Professor	College of Medicine, Yonsei University
Dr. Sang Soo Lee	Sr. Director, Government Affairs and Market Access, Medtronic Korea / Head, Center of Expertise, Government Affairs and Market Access, Medtronic Asia Pacific	Medtronic
Ji-Sun Lee	Principal Researcher	Korea Health Industry Development Institute (KHIDI), Center for Biohealth Policy & Research
Kit Tang	General Manager	Roche Diagnostics Korea
Cindy Pelou	Lead, Regulatory Affairs	APACMed
Jinsol Kim	Associate Principal	EVERSANA
Sunny Woo	Team Leader, International Affairs Team	Korea Medical Devices Industry Association (KMDIA)
Christine Choi	Head – HE&R Korea	Abbott
Jieun Lim	Head of Policy & Access	Roche Diagnostics Korea
Sangho Lee	Digital Business Manager	Roche Diagnostics Korea
Wonkyung Lee	RA Team Leader	Roche Diagnostics Korea
Jaejun Yim	CEO	Yideum Consulting Group
Young Woo Kim	CEO	MDREX
Soeun (Estella) Park	Regulatory Affairs Leads, Korea	Philips

United States of America

Tamara Syrek Jensen	Director, Coverage and Analysis Group, Centers for Clinical Standards and Quality, Centers for Medicare & Medicaid Services (CMS) (Prerecorded)	CMS Innovation Center at the Centers for Medicare and Medicaid
Jason Bennett	Director, Technology, Coding, and Pricing Group, Center for Medicare at Centers for Medicare & Medicaid Services (CMS) (Prerecorded)	CMS Innovation Center at the Centers for Medicare and Medicaid

Australia

Irina Tsyganova	Director, Prescribed List Administration Section (representing the Technology Access and Assessment Division)	Australian Government Department of Health and Aged Care
Steve Miller	Director, National Digital Health Infrastructure Policy	Australian Government Department of Health and Aged Care
Paul Creech	Chief Program Officer	Australian Digital Health Agency (observer)
Sophie Han	Director, Pathology Services Section	Australian Government Department of Health and Aged Care
Benish Aslam	Lead, Government Affairs and Policy & ESG	APACMed
Dr. Toby Hodgson	Senior Manager, Digital Health	MTAA
Paul Dale	Policy Director	MTAA
Sharon Leadbitter	Principal Associate Consultant, ANZ	EVERSANA
Ameera Abdullah	Regional Market Access Manager, ASEAN & Pacific	Philips
Mutsa Mutowo	Health Economics and Market Access Lead	Olympus
Doug Symonds	Senior Manager, Private Reimburse-ment, Medtronic Australasia	Medtronic
Simone Wagener	Head of Marketing, ANZ	Varian
Sebnem Erdol	Head of Market Access, Health Economics & Reimbursement, Australia and New Zealand	Abbott
Andrew Wiltshire	Head of Healthcare Public Policy, APAC	Amazon Web Services

France

Louisa Stüwe	Project Director, Digital Health Delegation	French Ministry of Health and Prevention

Japan

Anirudh Sen	Director & Head, Market Access & IVD	APACMed
Atsushi Sugihara	Partner, Japan Consulting Lead	EVERSANA
Yasuyo Tanaka	Senior Consultant	EVERSANA
Shinya Tsuruta	Medical Device Policy Office Manager	Ministry of Health, Labour, and Welfare
Shingo Kasahara	Managing Director	American Medical Devices and Diagnostics Manufactures' Association (AMDD)
Tamuro Makoto	Director, Medical Technology Policy Institute	American Medical Devices and Diagnostics Manufactures' Association (AMDD)
Dr. Rei Goto	Professor, Graduate School of Business Administration	Keio University
Jun Sekiguchi	Director of Government Affairs	Baxter
Dr. Shohei Nakano	Executive Director	Japan Association for the Advancement of Medical Equipment
Dr. Yuki Matsuhashi	Senior Researcher, Medical Device Strategy Institute	Japan Association for the Advancement of Medical Equipment
Go Ikeda	Senior Manager	Medtronic
Satoshi Ito	Director	Abbott
Koba Yuichiro	Senior Market Access and Reimbursement Manager	Philips
Masanori Otake	Director	GE HealthCare
Kanako Komagata	Digital Business Manager, Roche Information Solutions	Roche Diagnostics Japan